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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/715,055

11/17/2003

Gerald Cagle

1732 US F2

3314

26356

7590

04/04/2007

ALCON

IP LEGAL, TB4-8

6201 SOUTH FREEWAY

FORT WORTH, TX 76134

EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/715,055	<b>Applicant(s)</b> CAGLE ET AL.	
	<b>Examiner</b> Zohreh A. Fay	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Claims 11-58 are presented for examination.

The remarks file on January 19, 2007 have been received and entered.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al. (U.S. Patent 5,607,942). Peterson et al. teach the use of the claimed antibacterial agent in a pharmaceutical formulation for the treatment of ophthalmic infection. See column 54, line 22 and claim 2. The above reference makes clear that the claimed method of use is old and well known.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. (5,607,942) in view of Cagle et al. (WO 90/01933) and Bergamani et al. (U.S. Patent 5,597,560).

Peterson et al. teach the use of the claimed antibiotic, moxifloxacin in a pharmaceutical formulation for ophthalmic use. See Column 54, line 22 and claim 2. The above reference differs from the claimed invention in the presence of steroidal or non-steroidal anti-inflammatory agents. Cagle et al. teach the use of quinoline antibiotics in combination with steroidal anti-inflammatory agents. See page 1, lines 19-25. The claimed concentration range (0.01-2%) is taught in page 2, lines 19-21. Bergamini et al. teach the use of antibiotics with non-steroidal anti-inflammatory agents. See column 2, lines 37-60. It would have been obvious to add a steroidal or non-steroidal anti-inflammatory agent to the claimed antibiotics, considering that the secondary references teach the addition of anti-inflammatory agents to antibiotics for the treatment of inflammation associated with infection is old and well known.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of the claimed antibiotic for the treatment of ophthalmic infection, and the others relate to the use of antibiotics in combination with steroidal and non-steroidal anti-inflammatory agents as old. The use the well-known antibiotics taught for the treatment of ophthalmic infections in general, and use it for the treatment of specific ophthalmic infections, such as conjunctivitis is considered to be within the skill of the artisan. Applicant alleges criticality to the ability of moxifloxacin to penetrate the cornea at much higher level than ofloxacin. The allegation is not well taken. Applicant's attention is directed to *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594). It is noted that the above cases discuss the support of rejection wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited or is identical to product instantly claimed. In such situation the burden is shifted to the applicant to "prove that subject matter to be in the prior art does not possess the characteristics relied on" (205 USPQ 594, second column first full paragraph). There is no requirement that a person of ordinary skilled in the art would have realized the inherent disclosure at the time of invention, but only that subject matter is in fact inherent in the prior art reference. *Schering Co. v. Geneva Pharm Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004). The fact that the characteristic is a necessary feature or result of a prior art-embodiment is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh A. Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Z.F

